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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/130,887	08/07/1998	BRUCE G. GOLD	899-50283	6989

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EXAMINER

TURNER, SHARON L

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 08/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/130,887

Applicant(s)

GOLD, BRUCE G.

Examiner

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6, 7, 11, 15 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 7, 15 and 20 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☒ Claim(s) 6, 7, 11, 15 and 20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-10-03 has been entered.
2. The amendment filed 6-10-03 has been entered and fully considered.
3. Claim 19 is canceled. Claims 6-7, 11, 15 and 20 are pending.
4. Restriction is as set forth in Paper No. 15, mailed 12-15-00.
5. Applicant's election with traverse of Group III, claims 6-18 and 20 in Paper No. 15 is acknowledged. The traversal is on the ground(s) that the limitation "selecting (one) or more FK506 analogs comprises selecting one or more analogs that do not substantially inhibit FKBP-12 rotamase activity when administered to a patient at dosage levels up to about 100 mg/kg body weight/day," as recited in claim 19, is not a further method step but rather an inherent pharmacological characteristic of the selected FK-506 analog.

This argument has been fully considered but is not persuasive. The examiner understands applicants arguments to assert that FK-506 analogs inherently do not substantially inhibit FKBP-12 rotamase activity when administered to a patient at dosage levels up to about 100 mg/kg body weight/day. However, the examiner finds no such evidence of record to support this assertion. In contrast, it appears that the parent claims are directed to FK506 analogs which differentially bind FKBP-12 and differentially affect rotamase activity. Thus, it is presumed that the FK506 analogs of

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the invention differentially affect rotamase activity. Such effects may not necessarily be based upon the analogs individual FKBP-12 binding characteristics. Accordingly, it appears that the limitation serves to recite an additional step that is required for the selection of particular analogs (i.e., administration to patients), including evaluation of rotamase activity in patients which is not inclusive of binding. As the step is not encompassed by the parent claim, it is not further limiting, constitutes a new method and presents additional search burden to the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 6-7, 15 and 20 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,210,974. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim recitations of the '974 patent render obvious instant claims.

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In particular, the '974 patent teaches a method of identifying a compound that stimulates nerve cell growth wherein the compounds are non-FKBP-12 binding FK506 analogs (claim 3) that bind a polypeptide component of the steroid receptor complex wherein the test compounds bind to FKBP12 with an apparent K_d of greater than 100 μ M (claims 6 and 8). Thus the '974 claims render obvious the limitations of instant claim 6 with the same limitations. The claims further anticipate the method of claim 7 as the limitation of claim 7 is of a step not performed. As the step is also not performed in the '974 patent, the claims remain obvious over the '974 claims. Instant claim 15 is anticipated as the '974 patent teaches assaying the compounds for stimulating nerve cell growth. The assaying is understood by the artisan to be performed as disclosed in the '974 patent for example at columns 19-20 including exposing with the compound and measuring neurite outgrowth, and thus the patent renders obvious the same limitations of assaying comprising exposing the cell to the analog and determining if neurite outgrowth is promoted. Claim 20 is rendered obvious as the method merely recites that one or more analogs may be assayed using the same procedures as set forth in claim 6. The '974 patent similarly teaches that multiple compounds may be similarly assayed using the same screening procedures for example as indicated via the language of claim 1 indicating the test compounds in plural form may be tested. Thus, the '974 patent renders obvious the similar limitations to one or more FK506 compounds. Thus, for the aforementioned reasons the '974 patent renders obvious the invention claimed. A terminal disclaimer or other suitable amendment is appropriate.

Applicants argue in the response of 6-10-03 that the '887 application is the first filed and that the standard for ODP as set forth in MPEP 804 for such case must be found to be obvious in view of each other ("two-way obviousness"). In particular, Applicants argue that they could not have filed the claims of the two applications in a single invention because there was no support in the first filed '887 application for assaying the compound for inhibiting assembly of the steroid receptor complex or promoting dissociation of the complex. Further Applicant's argue that the '974 claims are directed to other compounds to be screened and that such compounds are not disclosed in the earlier application. Applicant's argue that the claims are not obvious because the '887 application does not disclose or suggest the method of the '974 patent directed to inhibiting assembly or promoting dissociation of the steroid receptor complex and that the compounds of the '887 application are not bezoquinone ansamycins, peptides comprising a sequence of the a polypeptide component of the steroid receptor complex, antibodies that bind it or geldanamycin derivatives. Moreover Applicant's assert that the issuance of the '974 patent prior is due to administrative delay.

Applicant's arguments filed 6-10-03 have been fully considered but are not persuasive. The '974 patent discloses and claims the preferred species of instant application, i.e., wherein the screening is of a FK506 analog which binds FKBP-12 with a K_d of greater than 100 μM , see in particular claims 3 and 8. Thus the species of the '974 patent anticipates the generic claims of instant case where the screening is also of FK-506 analogs and K_d for FKBP-12 of greater than 100 μM . Moreover, instant claims disclose a species of generic claim 1 in the '974 patent and could have

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anticipated the larger genus claims directed to polypeptide components of a steroid receptor complex and for inhibiting the assembly or promoting dissociation of the complex via binding to FKBP-12 with a K_d of greater than 100 μM as disclosed.

Moreover, no evidence of administrative delay on the part of the Office is shown. In contrast all submissions to the Office have been timely responded to by the Examiner in consult with SPE Gary Kunz or other Primary Examiner. It is noted that Applicant's have filed multiple extensions of time during the pendency of instant application. Thus, in contrast to Applicant's analysis, the Examiner finds no reason why the claims could not have been earlier presented or to evidence administrative delay on the part of the Office.

Claim Objections

8. Claim 11 stands objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Appropriate correction is required.

Status of Claims

9. No claims are allowed.

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued

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examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
August 25, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
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